UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,352	07/25/2003	Vladimir Knezevic	6457-65777	2321

7590 04/10/2006

KLARQUIST SPARKMAN, LLP
One World Trade Center
Suite 1600
121 S.W. Salmon Street
Portland, OR 97204

EXAMINER
YU, MELANIE J

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,352	KNEZEVIC ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 January 2006 has been entered.

Claims 1-46 are cancelled. Claims 47-50 are currently amended. Claim 53 is new. Claims 47-53 are currently pending in this application.

Withdrawn Rejections

2. Previous rejections under 35 USC 112, second paragraph have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. Newly amended claim 47 recites each membrane "having sufficient structural integrity to permit said separation in use". The original specification fails to provide support for the membrane having sufficient structural integrity to permit separation in use. It is noted that the original specification at page 12, lines 1-3, recites the substrate maintaining sufficient structural integrity despite being porous and very thin. The original specification does not provide support for sufficient integrity to permit separation in use.

4. Claims 47-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 47 recites each membrane having sufficient structural integrity to permit the separation in use. It is unclear what "the separation in use" refers to because "the separation" lacks antecedent basis. It is vague as to whether the limitation intends to recite having structural integrity to permit separation during use. Furthermore, it is unclear what structural limitations are required in order to provide sufficient structural integrity to permit separation during use. It is unclear whether the membrane must merely have a porous, polymeric substrate with the recited dimensions in order to have sufficient structural integrity or if further structural limitations are required or if certain structural elements, such as adhesive, must be excluded in order to permit separation. Furthermore, it is unclear whether each membrane must have sufficient structural integrity to be separated from itself or whether each membrane must have sufficient structural integrity to permit separation from the stack of membranes.

Claim Rejections - 35 USC § 103

1. Claims 47-49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodrum et al. (US 4,959,305) in view of Greenquist et al. (US 4,668,619) and Ciechanover et al. (US 5,384,255).

Woodrum et al. teach a kit comprising: a stack of separable membranes (carrier member with multiple layers encompasses a stack of layers that are formed separately and are therefore separable, col. 14, lines 46-61), each membrane comprising a porous, polymeric substrate (porous, col. 3, line 55-col. 4, line 12; polymeric, col. 9, lines 34-47) coated with a captor molecule for capturing one or more of the targeted biomolecules (binding partner, col. 16, lines 56-63); and detectors (labels, col. 16, lines 53-55). Although Woodrum et al. does not specifically teach the use of the kit or membranes separable after a capturing step is completed, such limitations are drawn to intended uses of the product and do not appear to provide any further structural limitations to the kit of the instant invention, and therefore the kit of Woodrum et al. is capable of use in the recited method and for separating membranes after completion of a capturing step. Woodrum et al. also fail to specifically teach each membrane having sufficient structural integrity to permit the separation in use. However, such a limitation does not appear to provide any further structural elements to the membrane. Since the membrane of Woodrum et al. comprises the recited structural limitations of being porous, polymeric and coated with a captor molecule, the membrane of Woodrum et al. is capable of having sufficient structural integrity to permit separation of a stack of membranes. Woodrum et al. fail to teach a specific pore size, a membrane thickness of less than 30 microns and containers comprising detectors.

Greenquist et al. teach a kit comprising: a stack of membranes separable from one another (carrier member with multiple layers encompasses a stack of layers that are formed separately and are therefore separable, col. 12, lines 5-11; col. 13, line 65-col. 14, line 7), each membrane comprising a biomolecule-permeable (impregnation of reagents indicates that layers are biopermeable, col. 11, lines 16-28), polycarbonate substrate (col. 12, lines 42-44) having a thickness 5-100 microns (col. 12, lines 50-54) which encompasses the recited less than about 30 microns, in order to permit transfer of targeted biomolecules therethrough (col. 11, lines 16-28).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Woodrum et al., polycarbonate substrates with a thickness of between 5 and 100 microns as taught by Greenquist et al., in order to provide increased permeability.

Ciechanover et al. teach containers comprising probe detectors, which are labeled antibodies (col. 19, lines 34-45), applied to a test strip (col. 16, lines 44-58) after target molecules are captured (col. 18, line 50-col. 19, line 26), in order to provide a simple yes/no assay for determination of the presence of an antigen.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Woodrum in view of Greenquist et al., containers comprising antibody detectors which are applied to the membranes after targeted biomolecules are captured as taught by Ciechanover et al., in order to perform a sandwich specific binding assay and provide close confinement storage for detector antibodies in a kit, which provide increased convenience and efficiency.

Woodrum et al. fail to teach a specific pore size of between about 0.1 to 5.0 microns. However it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 47 are for any particular purpose or solve any stated problem, and the prior art teaches that the pore size may be varied in order to permit analyte to permeate, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the porous membrane art.

Regarding claim 52, Woodrum et al. teaches 4 layers of porous material (col. 20, lines 22-40), but fail to specifically recite a stack comprising 5-10 membranes. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum

value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 52 are for any particular purpose or solve any stated problem, and the prior art teaches that the number of layers (membranes) can be varied in order to enhance and/or modulate the performance of a multilayer device, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the multilayer assay art.

2. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Woodrum et al. (US 4,959,305) in view of Greenquist et al. (US 4,668,619) and Ciechanover et al. (US 5,384,255), as applied to claim 47, and further in view of Pipas et al. (US 6,168,929).

Woodrum et al. in view of Greenquist et al. and Ciechanover et al., as applied to claim 47, teach a kit comprising containers comprising antibody detectors, but fail to teach a cocktail of antibodies.

Pipas et al. teach an antibody cocktail, in order to probe analytes blotted onto membranes (col. 17, lines 5-11).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Woodrum et al. in view of Greenquist et al. and Ciechanover et al., a detector comprising a cocktail of antibodies as taught by Pipas et al., in order to probe multiple target analyte.

3. Claims 47-49 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (US 6,218,134) in view of Ciechanover et al. (US 5,384,255).

Yamauchi et al. a kit comprising : a stack of separate membranes (reference letters, a and b, Fig. 11; layers are separated and sample is contacted with layers before separation which indicates a stack, col. 37, lines 5-27; col. 38, lines 25-33), each membrane comprising a porous (stack of porous nylon films, therefore each membrane is porous, col. 37, lines 20-23), polymeric (nylon is polymeric, col. 37, lines 20-23) substrate coated with a captor molecule for capturing one or more of the targeted biomolecules (nylon films have an immobilized antibody specific for the targeted biomolecule; b, Fig. 11; anti-hCGα antibody-immobilized porous nylon film, col. 37, lines 20-22); the porous, polymeric substrate having a thickness which is encompassed by less than 30 microns (total thickness of section b that can range in thickness from 10μm to several mm, therefore a total thickness of 10μm divided between 6 layers is a thickness encompassed by less than 30 μm, col. 28, lines 55-57) and a pore size of 3.0 microns (porous matrix described in example 1, col. 34, lines 61-67; is used in example 2 and therefore has the same pore size, col. 36, lines 55-57), and having sufficient structural integrity to permit separation during use (matrix elements are separated and each section measured, col. 37, lines 20-27); and a detector for identifying a biomolecule captured on a separated membrane (labeled antibody, col. 37, lines 36-42, label is a detector for identifying a biomolecule). Yamauchi et al. fail to teach the detectors in a container.

Ciechanover et al. teach containers comprising probe detectors, which are labeled antibodies (col. 19, lines 34-45), applied to a test strip (col. 16, lines 44-58), in order to provide a simple yes/no assay for determination of the presence of an antigen.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Yamauchi et al., containers comprising antibody

detectors as taught by Ciechanover et al., in order to perform a specific binding assay and provide close confinement storage for detector antibodies in a kit, which provide increased convenience and efficiency.

Regarding claims 48-49, Yamauchi et al. teach the detector comprising antibody probes for α-galactosidase-HM81 (antibody is labeled and therefore the label comprises an antibody which is a probe, col. 37, lines 23-25).

With respect to claims 52 and 53, Yamauchi et al. teach a stack of 6 layers of antibody-immobilized nylon membranes (b, Fig. 11; col. 37, lines 36-42), which is encompassed by the stack comprises 5-10 membranes and at least 5 membranes.

4. Claim 50 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (US 6,218,134) in view of Ciechanover et al. (US 5,384,255) further in view of Pipas et al. (US 6,168,929).

Yamauchi et al. in view of Ciechanover et al., as applied to claim 47, teach a kit comprising containers comprising antibody detectors, but fail to teach a cocktail of antibodies.

Pipas et al. teach an antibody cocktail, in order to probe analytes blotted onto membranes (col. 17, lines 5-11).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Yamauchi et al. in view of Ciechanover et al., a detector comprising a cocktail of antibodies as taught by Pipas et al., in order to probe multiple target analyte.

5. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (US 6,218,134) in view of Ciechanover et al. (US 5,384,255) further in view of Metcalfe et al. (US 4,539,294).

Yamauchi et al. in view of Ciechanover et al., as applied to claim 47, teach a kit comprising a stack of polymeric substrates, but fail to teach the polymeric material being polycarbonate.

Metcalfe et al. teach a kit comprising a porous membrane wherein the substrate is a nylon or polycarbonate substrate (col. 3, lines 9-15), in order to provide a porous substrate for immobilization of biomolecules.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the kit of Yamauchi et al., polymeric substrates made of polycarbonate as taught by Metcalfe et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent material for immobilization of biomolecules and since the same expected immobilization effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Response to Arguments

6. Applicant's arguments filed 20 January 2006 have been fully considered but they are not persuasive.

Regarding the rejection of claims 47-49 and 51 under 35 USC 103(a) over Woodrum et al. in view of Greenquist et al. and Ciechanover et al., applicant argues that the separability of

membranes of the kit is not taught by Woodrum, Greenquist or Ciechanover. Applicant argues that Woodrum does not specifically teach that the layers have sufficient structural integrity to permit separation from one another because the multilayer device of Woodrum permits fixation of layers into a laminar relationship with one another. However, in response to applicant's arguments, applicant does not recite specific structural limitations required to permit separation from one another. Therefore any product having the structural limitations recited by the instant claims is assumed to have sufficient structural integrity. Furthermore, separation of membranes or the limitations of the membranes being separable does not provide any further product limitations to the membrane. Although the multilayer device of Woodrum permits the fixation of layers in a laminar relationship and does not specifically teach separation of the membranes, this does not exclude the possibility of separation of membranes or the membranes having sufficient structural integrity to permit separation. The device of Woodrum must merely be *capable* of separation and be made of a material that is *capable* of having sufficient structural integrity for separation. Since the substrates of Woodrum are made of the material required by the instant claims, the substrates therefore have sufficient structural integrity and are therefore capable of separation. If other structural elements are required to permit separation (ie. exclusion of adhesive or inclusion of other materials required for structural integrity) such elements should be recited in the claims.

Applicant also argues that the layers of the multilayer device of Woodrum are composed of 5% gelatin, 10% gelatin or 1% agarose. However, these materials are not excluded by the rejected claims and as required by the rejected claims, the layer must merely comprise a

polymeric material. Since the layers of Woodrum et al. are polymeric, as described above, the inclusion of any gelatin or agarose does exclude the substrate comprising a polymeric material.

Applicant further argues that Woodrum does not teach a specific pore size, a specific membrane thickness or containers. However, Woodrum is not relied upon for containers and dimensions may be optimized as described above.

Applicant argues that Greenquist do not teach membranes having sufficient structural integrity for separation, specific pore size or containers. Applicant also argues that Ciechanover do not teach specific pore size, thickness or a membrane having sufficient structural integrity for separation. Applicant further argues that Pipas fails to teach a stack of separable membranes that have sufficient structural integrity to permit separation. However, in response to applicant's arguments, Greenquist, Ciechanover and Pipas are not relied upon for the teachings of these elements.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/31/06